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IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP. and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	Case No. 08-CV-0133 RMW **DEFENDANT SENORX, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8)** Date: June 25, 2008 Time: 2:00 p.m. Courtroom: 6, 4th Floor Judge: Hon. Ronald M. Whyte

ARGUMENT IN REPLY

At issue here is the critical public notice function of patent claims. Claims 1 and 8 of the '142 patent, as they are actually drafted, lead to an inoperable invention. Plaintiffs insist this Court should fix their error in drafting an inoperable claim, but to do so the Court would have to selectively ignore, contort and rewrite the language of the claim. This the Court cannot do.

What Plaintiffs seek is contrary to the "'bedrock principle' of patent law that 'the claims of a patent define the invention.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (citation omitted). It is contrary to the statutory requirement that the claims "particularly point[] out" and "distinctly claim[] the subject matter" regarded as their invention. 35 U.S.C. § 112. And it is "unjust to the public," *White v. Dunbar*, 119 U.S. 47, 52 (1886), particularly competitors such as SenoRx who are entitled to rely on claims as written. Patent claims serve the critical public policy of "'appris[ing] the public of what is still open to them.'" *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) (*quoting McClain v. Ortmayer*, 141 U.S. 419, 424 (1891)). If patent claims can be construed to mean virtually anything, as Plaintiffs maintain, this public notice function will fail.

1. Public Notice.

SenoRx construes the claimed "apparatus volume" as a "volume," *i.e.*, a region of space. This is based on the language of the claim and the plain and ordinary meaning of the term, and is consistent with the use of the disputed term "apparatus volume" in the specification.

Plaintiffs criticize SenoRx for its "literal interpretation of the claim language." Pls. Br. at 5. SenoRx does indeed base its construction on the notion that the language of the claim means what it says, but this is not grounds for criticism. Instead, it is exactly what is required by the patent laws and over a century of established case law, and ensures the public notice function of the patent is met. *White v. Dunbar*, 119 U.S. 47, 52 (1886).

Plaintiffs argue that SenoRx's "literal interpretation of the claim language" (*i.e.*, that the claim means what it says) is erroneous because it is a "rigid" interpretation "divorced from the context of the specification." Pls. Br. at 5. Not so. To the contrary, the specification clearly indicates that the definition of "apparatus volume" set forth in the claim itself, *i.e.*, the "three-

dimensional" volume "defin[ed]" by the expandable outer surface that "fill[s]" the surgical cavity, is the correct one. The specification teaches that the "present invention" of the '142 patent has "an expandable outer surface element defining an apparatus spatial volume." Ex. 1[1] ('142 patent), col. 2:55-64. This language tracks the language of the claim, and by its use of the adjective "spatial," shows that the plain reading of "apparatus volume" as a region of space is correct. So too the portion of the specification reciting an "outer spatial volume defined by an outer polymeric film barrier," cited by Plaintiffs in support of their position. Pls. Br. at 8 (emphasis added). But this does not support Plaintiffs; instead, it again makes clear that when the patent refers to a "volume," it is referring to a "spatial volume," *i.e.*, a region of space defined by a surface. This is precisely the issue that arose in the *Xoft* case, where Plaintiffs took the opposite position of the one they argue here:

> The "outer spatial volume" is a region of space that is defined by an "expandable surface element" but it is not the "expandable surface element" itself. . . . [T]he term should be construed as "a region of space defined by an expandable surface element . . . ." This is consistent with the ordinary meaning of the claim term in view of the specification.

Ex. 2[2] (Cytyc Br.) at 19:21-28 (emphasis added). The specification supports the language of the claim (and SenoRx's construction of the claim as meaning what it says) – the apparatus volume is a region of space defined by an expandable outer surface.

Plaintiffs reverse the importance of the claims and specification in their approach to construing "apparatus volume." Plaintiffs do not start with the claim language, and interpret it in light of the specification. *Phillips*, 415 F.3d at 1312-13. Instead, Plaintiffs realize that the claim as written is nonsensical and turn to the specification as though it were a substitute for the claim language. But while the specification is an important guide for understanding the claim language, it does not supplant the definitional function of the claims. *Phillips*, 415 F.3d at 1312-13. The

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[1] Ex. 1 is an exhibit to the Declaration of Adam D. Harber in Support of SenoRx, Inc.'s Motion for Partial Summary Judgment of Invalidity.

[2] Exs. 2-4 are exhibits to the Declaration of Adam D. Harber in Support of SenoRx, Inc.'s Reply in Support of its Motion for Partial Summary Judgment of Invalidity.

notice function of claims does not permit this: "The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language. Specifications teach. Claims claim." *Superguide Corp. v. DirecTV Enters.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (citation and quotations omitted); *see also Aro Mfg. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("The claims made in the patent are the sole measure of the grant . . . .").

Indeed, Plaintiffs' objections to SenoRx's construction do not derive from the claim language actually defining the disputed "apparatus volume" limitation in the first clause of the claim 1. Rather, it is because the second clause of claim 1 requires that the radiation source is "spaced apart from the apparatus volume" at the same time it is "completely within" the surface defining that volume – an impossibility – that Plaintiffs seek to rewrite the meaning of "apparatus volume" in the first clause. That is plainly improper. Neither Plaintiffs nor the Court is empowered to redraft the claim to give a different meaning to "apparatus volume" in order to resolve the problem that arises from the plain meaning of the second clause of the claim, even to avoid a nonsensical result. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356-57 (Fed. Cir. 1999). Doing so completely undermines the bedrock purpose of claim language in providing the public with notice of the scope of the claims and "unduly burden[s] competitors who must determine the scope of the claimed invention based on an erroneously drafted claim." *Id.* at 1357. "Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999); *see also Process Control*, 190 F.3d at 1357 ("[W]e do not permit courts to redraft claims."); *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("[I]t is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.").

For authority to ignore this precept, Plaintiffs rely on the Federal Circuit's statement that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Modine Mfg. Co. v. United States Int'y Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996). But this is just such a rare case. It is a rare case that the prosecuting attorney claims an impossibility, a rare case that it is so clear that the claim is nonsensical as written, and a rare case that patentees would struggle like Plaintiffs here to ignore the plain meaning of the language

of their claim. [redacted] If Plaintiffs had wanted to redraft the claims to be consistent with the constructions it favors in this litigation, they should have done so in prosecuting the patent before the Patent Office. But they took no such action.[3]

2. Ortho-McNeil Pharmaceuticals v. Mylan Laboratories, Inc.

Plaintiffs suggest that *Ortho-McNeil Pharmaceuticals v. Mylan Laboratories, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008), distinguishes the cases cited by SenoRx in its opening brief (*Process Control*, *Chef America*, *Allen Engineering*), and mandates this Court rewrite the claims to preserve their validity. Pls. Br. at 6. Not so. Although *Ortho-McNeil* determined that the claim at issue in that particular case was not nonsensical, it also reaffirmed (just like *Process Control* and the other cases relied on by SenoRx) that claims cannot be rewritten to preserve their validity if, as here, the only reasonable construction is one that is nonsensical. The limitation in question in *Ortho-McNeil* stated that the claimed drug encompassed two possible formulas, one where

[3] Furthermore, it is not true that every claim need cover the preferred embodiments. On June 4, 2008, the Federal Circuit in *Helmsderfer et al. v. Bobrick Washroom Equipment, Inc., et al.*, ___ F.3d ___ (Fed. Cir. 2008), upheld a construction in which claims "[did] not cover the preferred embodiment or the other illustrated embodiments." *Id.*, slip op. at 7. In so doing, the Court distinguished *Vitronics*, and other cases cautioning against construing claims to exclude preferred embodiments, as limited to situations where a claim term "has multiple ordinary meanings consistent with the intrinsic record." *Id.* at 6. The Court further reasoned that, where some claims cover the disclosed embodiments, the fact others do not is not a barrier to construing the claims according to the language "the patentee chooses . . . ." *Id.* at 7. Here, as in *Helmsderfer*, claim 1 should be construed according to the language the patentee chose. There is no "ordinary meaning[]" of apparatus volume other than as a "volume." And furthermore, the other claims of the patent plainly cover the disclosed embodiments. *E.g.*, *compare* Ex. 1, '142 patent, claim 2 *with* Figure 1. Accordingly, the inventors here are not being denied their invention by SenoRx's construction; instead, the public notice function of the claims is being upheld.

certain molecules were "independent[]" and one where those same molecules formed a "group."[4] *Id*. at 1361. Because those two variations were claimed with an "and" between them, the accused infringer argued that a drug had to meet both variations to infringe, which is impossible. The Federal Circuit held instead that there was a reasonable reading of "and" – that it was disjunctive – and that such a reading was consistent with the claim's recitation of "independently" and "together." The Federal Circuit then looked to the "larger context of the patent," *id.* at 1362, to confirm this understanding of how "and" was used, starting with the language of the other claims and then turned to the specification. The Court concluded that "and" consistently was used to be disjunctive.

As described in detail in SenoRx's claim construction briefing, following that same process here dooms claim 1 of the '142 patent. "Apparatus volume" is defined in the claim itself as the region of space within the expandable outer surface that fills the surgical cavity. This definition is the only one that makes sense of the use of "apparatus volume" in the other claims of the patent. *E.g.*, Claim 3 ("a catheter in communication with the apparatus volume"); Claim 4 (an "elongate member . . . taking on a substantially straight shape while being inserted through the catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume"); Claim 6 ("two elongate members extending into the apparatus volume"); *cf.* Claim 9 ("a radiation source disposed completely within and spaced apart from the expandable outer surface"). And, as discussed above, the specification consistently refers to the apparatus volume as a "spatial volume," *i.e.*, a region of space, defined by the expandable outer surface. There is but one reasonable construction of apparatus volume that is consistent with claim 1, the other claims and the specification – the "apparatus volume" is the region of space defined by the expandable outer surface that fills the void. Accordingly, claim 1 (and dependent claim 8) require an impossibility and should be held to be invalid.

[4] "R2, R3, R4, and R5 are independently hydrogen or lower alkyl and R2 and R3 and/or R4 and R5 together may be a group of formula (II) (emphasis added)." *Ortho-McNeil*, 520 F.3d at 1361.

3. Plaintiffs' Construction of "Apparatus Volume" Means that Claims 1 and 8 are Inoperable and Not Enabled.

Even should this Court adopt Plaintiffs' construction of "apparatus volume," claims 1 and 8 still are invalid for inoperability and lack of enablement. In his report on claim construction, Plaintiffs' expert, Dr. Verhey opines that the "apparatus volume" of claim 1 "is a three-dimensional geometric solid (*e.g.*, a sphere) having both volume that fills an interstitial void created by the surgical extraction of diseased tissue and a surface area that defines an inner boundary of the target tissue being treated." Ex. 4 (Verhey Decl. (May 21, 2008)) at 5:4-10 (emphases added). Plaintiffs explain, "by way of analogy," that the expandable outer surface of the claimed device defines an "apparatus volume" the same way "the skin of a basketball defines a three-dimensional basketball." Pls. Cl. Constr. Br. at 22, n.14.

If the "apparatus volume" encompasses "both volume . . . and a surface area," the claim limitation that the radiation source is "located so as to be spaced apart from the apparatus volume" must be understood to require that the radiation source is "located so as to be spaced apart" from both the volume and the surface area. To further Plaintiffs' basketball analogy, a radiation source that is "located so as to be spaced apart from the basketball" must mean that the radiation source is outside of the basketball. Accordingly, not even Plaintiffs' construction of "apparatus volume," as contorted as it may be, saves claim 1.

Plaintiffs tacitly acknowledge this by attempting to rewrite their own construction of "apparatus volume" as used in the "spaced apart" limitation. There, instead of staying true to their own construction that "apparatus volume" is "both" the expandable outer surface of the device and the volume within it, Plaintiffs assert instead that it means only the surface:

> A radiation source can thus be "disposed completely within" the volume that fills the interstitial void and "spaced apart from" the surface that defines the inner boundary.

Pls. Br. at 8. But this is precisely the opposite of what claim 1 says:

> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume

Ex. 1, claim 1. The claim does not say that the radiation source is "disposed completely within" the volume – it says "disposed completely within the expandable outer surface." And the claim does not say that the radiation source is "spaced apart from" the surface – it is "spaced apart from the apparatus volume."

If Plaintiffs are contending that "apparatus volume" means solely the "expandable outer surface" in the "spaced apart" limitation, why did they not simply say that the apparatus volume is equivalent to the surface (as they did in the hearing for a preliminary injunction)? Because, as SenoRx pointed out at the hearing, such a reading renders the first element of claim 1 equally nonsensical, as it would read "an expandable outer surface defining an expandable outer surface" under that definition.[5] But that is precisely the result Plaintiffs urge by their argument that the "apparatus volume" in the "spaced apart" limitation is only the surface. This should be rejected.

Plaintiffs' current position can be summarized as follows:

- In the first half of the claim, the apparatus volume "is a three-dimensional geometric solid (e.g., a sphere) having both volume . . . and a surface area." *Id.* at 5:4-10.
- But in the second half of the claim, the "apparatus volume" refers to only the surface of the apparatus volume.[6]

This construction is more than "somewhat unusual," which is how even Plaintiffs' own expert described the construction in his own expert report. Ex. 4 (Verhey Decl. (May 21, 2008)), at 5:11-12 (emphasis added). It is an unreasonable construction.

[5] In the preliminary injunction proceedings, the Court noted its "concern that Hologic does not [seem] to be able to propose an alternate construction of this limitation." PI Order at 16. It is not surprising that when Plaintiffs finally do supply a definition of "apparatus volume," the definition changes depending on where (and when) it is used by Plaintiffs; the definition makes no sense and is completely contrary to the claim language.

[6] Plaintiffs seek here a ruling that the second half of the claim requires a radiation source disposed within and spaced apart from the expandable outer surface. This is not what claim 1 states. It is, however, what is plainly spelled out in claim 9, which states that the radiation source is "disposed completely within and spaced apart from the expandable outer surface." If Plaintiffs had wanted claim 1 to read this way, they should have drafted it to read that way during the prosecution of the patent, as was done with claim 9. Instead they chose different language, apparently seeking a different result. They should not be able to divorce themselves from that which they sought now, in contravention of the public notice function of what they claimed.

Under any reasonable construction (and SenoRx submits that there is only one), the claim is inoperable and invalid.

4. There Is No Factual Dispute.

Plaintiffs suggest that SenoRx's motion is deficient because it is not accompanied by any "supporting affidavits from an expert or otherwise." Pls. Br. at 3. That is a complete red herring. There is no dispute as to the relevant facts; indeed, Plaintiffs concede as much, agreeing that reading the claims as SenoRx contends leads to a "nonsensical" result. Pls. Br. at 2.

The basis for SenoRx's motion, as plainly set forth in SenoRx's opening brief, is that it is impossible for a radiation source to be "disposed completely within" the outer surface of the device and also at the same time to be located outside that same outer surface. *E.g.*, SenoRx Op. Br. at 1 ("SenoRx requests the Court hold claims 1 and 8 of the '142 invalid on the grounds that, as a matter of law, they are inoperable and not enabled since the radiation source recited in claim 1 cannot simultaneously be 'within' the claimed outer surface and 'spaced apart' from the claimed volume defined by that surface. As claim 8 depends from claim 1, it incorporates all of claim 1's limitations (and flaws as to operability and enablement) as a matter of law."); *see also id.* at 4, 9. Plaintiffs cannot and do not dispute this. It is absurd to suggest that an affidavit from an expert is required to reach this conclusion, which is not only self-evident, but as to which all parties agree.

What claims 1 and 8 mean is a matter of claim construction, *i.e.*, a matter of law. If the Court construes the claims according to SenoRx's construction, the claims recite a factual impossibility and thus are not enabled and inoperable as a matter of law. That a radiation source cannot simultaneously be both within a surface and outside the surface is plainly true, and Plaintiffs have not identified any evidence or argument to the contrary. As the controlling rule clearly states, and the Supreme Court squarely has held, SenoRx was not required to put in an affidavit as to this undisputed fact. *See* Fed. R. Civ. P. Rule 56(b) (explaining that party may move for summary judgment "with or without supporting affidavits") (emphasis added); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) ("[W]e find no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the

opponent's claim.").

CONCLUSION

Since the radiation source of claim 1 cannot simultaneously be "within" the outer surface and "spaced apart" from the volume defined by that surface, claim 1 is inoperable and invalid. As claim 8 depends from claim 1, it too should be declared invalid for the same reasons.

Respectfully Submitted,

Dated: June 11, 2008

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

By: /s/ F.T. Alexandra Mahaney
F.T. Alexandra Mahaney
amahaney@wsgr.com

Attorneys for Defendant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Janice Wright, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On June 11, 2008, I served a copy(ies) of the following document(s):

DEFENDANT SENORX, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY ('142 PATENT, CLAIMS 1 AND 8) [REDACTED VERSION]

on the parties to this action by the following means:

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☐ (BY PERSONAL SERVICE) I caused to be delivered by hand to the addressee(s) noted above. I delivered to an authorized courier or driver to be delivered on the same date. A proof of service signed by the authorized courier will be filed with the court upon request.

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☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on June 11, 2008.

Janice Wright

Janice Wright

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SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP. and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	Case No. 08-CV-0133 RMW **DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT SENORX, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY** Date: June 25, 2008 Time: 2:00 p.m. Courtroom: 6, 4th Floor Judge: Hon. Ronald M. Whyte

I, Adam D. Harber, declare that I am an associate at the law firm of Williams & Connolly LLP, admitted pro hac vice to practice before this Court in the above-captioned matter. I serve as outside counsel for Defendant SenoRx, Inc. The following declaration is based on my personal knowledge, and if called upon to testify, I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit 2[1] is a true and correct copy of Cytyc Corporation's (and Hologic's predecessor Proxima Therapeutics') Opening Claim Construction Brief (Docket No. 48), from the case captioned Xoft, Inc. v. Cytyc Corp., et al., Case Number C-05-05312 RMW, in the United States District Court for the Northern District of California.

2. Attached hereto as Exhibit 3 is a true and correct copy of excerpts of the transcript of the Deposition of Timothy J. Patrick (May 29, 2008).

3. Attached hereto as Exhibit 4 is a true and correct copy of the Declaration of Lynn J. Verhey, Ph.D. in Support of Hologic's Proposed Construction of Claim Terms, Phrases and Clauses (excluding the exhibits), which was attached as Exhibit H to the Declaration of Katherine L. Altemus in Support of Plaintiffs' Opening Claim Construction Brief.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 11, 2008

By: _____
Adam D. Harber

[1] The numbers assigned to exhibits attached to this Declaration run consecutively from the exhibit numbers of those attached to the Declaration of Adam D. Harber in Support of Defendant SenoRx, Inc.'s Motion for Partial Summary Judgment of Invalidity.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Janice Wright, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On June 11, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF ADAM D. HARBER IN SUPORT OF DEFENDANT SENORX, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY

on the parties to this action by the following means:

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Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

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I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on June 11, 2008.

Janice Wright

Janice Wright

Exhibit 2

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

XOFT, INC., Plaintiff, vs. CYTYC CORPORATION and PROXIMA THERAPEUTICS, INC., Defendants. AND RELATED COUNTERCLAIMS.	Case No. CV 05-05312 RMW **DEFENDANT AND COUNTERCLAIMANT CYTYC CORPORATION'S OPENING CLAIM CONSTRUCTION BRIEF (PAT. L.R. 4-5(a))** Tutorial and Markman Hearing Date: December 20, 2006 Time: To Be Set Room: Courtroom 6, 4th Floor Judge: Hon. Ronald M. Whyte

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CASES

STATUTES

Pursuant to the Agreed Scheduling Order,[1] Defendant and Counterclaimant Cytyc Corporation ("Cytyc") respectfully submits this Brief addressing the construction of disputed terms, phrases and clauses in the asserted claims of U.S. Patent Nos. 5,913,813 (the "'813 patent") and 6,413,204 (the "'204 patent") (attached hereto as Exhibits A and B to the Declaration of Henry C. Su, respectively). Cytyc currently asserts claims 1, 2, 3, 4, 8 and 12 of the '813 patent and claims 1, 2, 3, 4, 8, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 30, 32, 34, 35 and 36 of the '204 patent against Plaintiff Xoft, Inc. ("Xoft").

PRELIMINARY STATEMENT

The differences in the parties' approaches to construing the disputed terms are stark. Cytyc's proposed constructions are straightforward, applying the plain meaning that would be apparent to one of ordinary skill in the art when the disputed terms are read in light of the specification, in accordance with the Federal Circuit's recent *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), *cert. denied,* 126 S. Ct. 1332 (2006). In contrast, Xoft insists on improperly injecting into its proposed constructions of the disputed terms limitations that are nowhere found in the claim language and are not supported by the specification, in contravention of Federal Circuit law. Xoft also repeatedly attempts to limit the claim terms to exemplary embodiments in the specification, which is also contrary to the law. In a few instances where the patent specifically defines a claim term, Xoft refuses to acknowledge that express definition, crafting instead its own definition from whole cloth. Finally, Xoft cannot hope to establish by clear and convincing evidence that certain claims terms are indefinite. The testimony of Cytyc's expert, Dr. Lynn J. Verhey, shows that one skilled in the art, reading the disputed terms in light of the specification, understands exactly what is being claimed. Xoft's strained interpretations of the disputed terms and its meritless allegations of indefiniteness should thus be rejected.

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[1] The Agreed Scheduling Order called for Cytyc to file its Opening Claim Construction Brief on November 6, 2006. On account of the fact that the Court was moving the date for the technology tutorial and claim construction hearing from December 6-7, 2006 to December 20, 2006, the parties filed on November 3, 2006 a joint stipulation and proposed order requesting that the Court enlarge the briefing schedule. On November 7, 2006, the Court declined to enlarge the briefing schedule (other than to set the due date for the reply brief on December 7, 2006) and held that "[h]aving at least the minimum time periods set forth in Civil L.R. 7 to consider the parties' arguments would be particularly useful to the court in a case such as this." In response to this order, Cytyc moved promptly to finalize and file its Opening Claim Construction Brief, which is still being submitted more than 35 days before the scheduled hearing date.

BACKGROUND

I. THE TECHNOLOGY

The patents-in-suit relate to the field of treating proliferative tissue diseases like cancer with radiation. Traditionally, a patient diagnosed with a cancerous tumor would have the tumor removed and then the region of body where the tumor was located would be exposed to an external radiation beam in an attempt to ensure that any remaining cancerous cells are destroyed. One of the major disadvantages of external beam radiation therapy is that it is difficult to target just the diseased area and avoid irradiating significant portions of healthy tissue. Accordingly, it is medically desirable to use various devices and instruments to position the radiation source as close as possible to the diseased site. This technique is known as brachytherapy. The root "brachy" comes from the Greek word for "short distance."

The patents-in-suit are directed specifically to a type of brachytherapy known as interstitial brachytherapy, in which the radiation source is introduced in close proximity to diseased cells that are within the interstices of a body tissue. This technique requires creating some sort of path through the tissue to the reach the targeted site, and it can be contrasted with brachytherapy in which the radiation source is merely inserted into a natural body cavity like the bladder (intracavitary), into a body lumen like the urethra (intraluminal), or on the surface of the body (surface brachytherapy). For example, as taught by the patents-in-suit, a radiation source is introduced through the opening and cavity created by the tumor resection so that it can treat the diseased cells within the interstices of the tissue at the margins of the tumor resection site.

According to the invention described and claimed in the patents-in-suit, the radiation source is introduced into the resection cavity using a catheter. An expandable or inflatable device, such as a cage or balloon, is used to shape the resection cavity so that the radiation dose absorbed by the diseased cells within the interstices of the tissue at the margins of the cavity is made more uniform. Three primary factors affect the amount of the absorbed dose: (1) distance of the tissue to be treated from the radiation source, (2) the presence of a radiation attenuating medium such as air or a saline solution, and (3) the use of radiation shielding.

The patents-in-suit use these factors, individually or in combination, to improve treatment by controlling the "radial absorbed dose profile" and the "three-dimensional isodose profile." The former involves controlling the absorbed dose as a function of radial distance from the radiation source to points within the targeted tissue; the latter involves conforming the shape of the targeted tissue to a virtual, three-dimensional surface defined by points receiving the same radiation dose. To control the radial absorbed dose profile, one may surround the radiation source with a radiation attenuating medium to minimize the ratio of the absorbed dose at the wall of the tumor cavity to the dose within the interstices of the target tissue. If the ratio is too high, then "hot spots" can occur at the wall of the cavity, which cause healthy tissue to necrose. Controlling the three-dimensional isodose profile involves shaping the resected tumor cavity and adjusting the position of the radiation source relative to the cavity to create a desired, virtual isodose surface on which all points receive substantially the same dose. These points will be coincident with points within the interstices of the tissue to be treated.

II. THE EXPERTS

Although Cytyc bases its proposed constructions on the intrinsic evidence, *i.e.*, the patents' claim language, specifications, and prosecution histories, Cytyc also proffers the testimony of Dr. Lynn J. Verhey to provide the perspective of one skilled in the relevant art. *Phillips*, 415 F.3d at 1313 (claims must be construed from the perspective of one skilled in the art). In this case, a person of ordinary skill in the art has a background in radiation oncology physics with a focus on brachytherapy. Such individuals would hold a M.S. degree in Physics or Engineering, with 3 or more years of clinical medical physics experience, or a Ph.D. in Physics or Engineering with 2 or more years of clinical experience. (*See* Exhibit D to the Declaration of Henry C. Su (Declaration of Lynn J. Verhey, Ph.D. ("Verhey Rep.")) at 4:6-18.)

Dr. Verhey is an expert in the field of radiation oncology, with decades of experience. He is currently a Full Professor and Vice-Chair in the Department of Radiation Oncology at University of California, San Francisco. Dr. Verhey earned a Ph.D. in Physics and, in 1975, took a position as Hospital Radiation Physicist at Massachusetts General Hospital (MGH) with a concurrent continuing position as Assistant Professor at the Harvard Medical School. In 1990, he became Chief of the Physics Division and Associate Professor in the Department of Radiation Oncology at UCSF. He has

taught courses in physics, radiation, and medical physics (including radiation oncology). He has conducted research on new methods of delivering radiation to cancer patients and has published over 100 technical papers in that field. Dr. Verhey is a certified Therapeutic Radiological Physicist by the American Board of Radiology and is a fellow in the American Association of Physics in Medicine and the American Society of Therapeutic Radiology and Oncology. In sum, he is a well-recognized and independent expert in methods of delivering radiation to cancer patients.

By contrast, Xoft's expert, Paul A. Lovoi, Ph.D., did not attach a curriculum vitae to his report and his credentials in the relevant field are not otherwise apparent. Moreover, Dr. Lovoi is not independent. He is one of the founders of Xoft and was an officer of Xoft until recently. He now consults for Xoft and has worked for the company during the last decade. His report indicates a Ph.D. in physics but does not list any specific experience in the field of radiation oncology, other than 9 years of purported experience in "medical use of sources of radiation." Xoft is Dr. Lovoi's company – he founded it, he ran it, and he has devoted a good part of his life to it. This Court should weigh his opinions accordingly.

APPLICABLE LAW

Sitting *en banc*, the Federal Circuit recently clarified its guiding principles for construction of patent claims. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). In *Phillips*, the court emphasized the "primary importance" of the language of the claims themselves:

> It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." . . . That principle has been recognized since at least 1836, when Congress first required that the specification include a portion in which the inventor "shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." . . . In the following years, the Supreme Court made clear that the claims are "of primary importance, in the effort to ascertain precisely what it is that is patented." . . . Because the patentee is required to "define precisely what his invention is," the Court explained, it is "unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." . . .

415 F.3d at 1312 (citations omitted). The Federal Circuit also reaffirmed the time-honored rule that claim terms are generally to be given their ordinary and customary meaning to those skilled in the art:

> We have frequently stated that the words of a claim "are generally given their ordinary and customary meaning." . . . We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective

> filing date of the patent application. . . . The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.

Id. at 1312-13 (citations omitted). Likewise, the court stressed that claims must be read in light of the specification. *Id.* at 1315 ("claims must be read in view of the specification, of which they are a part.") (internal quotations omitted)). Importantly, the court held that claim terms should be given "*their broadest reasonable construction* 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *Id.* at 1316 (citing *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (emphasis added).

The *Phillips* court repeated the venerable warning that one must "avoid the danger of reading limitations from the specification into the claim." 415 F.3d at 1323. With that warning in mind, the court described the two primary instances in which the specification can limit the meaning of claim terms. *First*, the patentee can choose to recite an explicit definition for a claim term in the specification. *Id.* at 1316. In that case it is said that the patentee has acted as his own lexicographer and the patentee's definition "governs." *Id. Second*, the specification may limit the plain meaning of a claim term when the patentee disclaims or disavows certain interpretations of the term. *Id.* In other words, the specification can limit the plain meaning of claim terms when the patentee has clearly set forth a limiting interpretation.

The prosecution history is also important to consider when construing claim terms. The *Phillips* court explained:

> [W]e have held that a court "should also consider the patent's prosecution history, if it is in evidence." . . . The prosecution history, which we have designated as part of the "intrinsic evidence," consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. . . . Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent. . . . Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent.

415 F.3d at 1317 (citations omitted).

The *Phillips* court also noted that expert testimony (on which Xoft almost exclusively relies in this case) should play a lesser role in claim construction. 415 F.3d at 1317 ("[W]hile extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than

the intrinsic record in determining the legally operative meaning of claim language.'") (internal quotations omitted). The court added that:

> extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field. . . . However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, *a court should discount any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent."*

Id. at 1318 (emphasis added; citations omitted).

One claim limitation from the '813 patent uses the term "means," which creates a presumption that the limitation is drafted in "means plus function" format pursuant to 35 U.S.C. § 112, ¶ 6. *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996). "Construction of a means plus function limitation requires identification of the function recited in the claim and a determination of what structures have been disclosed in the specification that correspond to the means for performing that function." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1032 (Fed. Cir. 2002). Structure described in the specification constitutes "corresponding structure" if the specification "clearly links or associates that structure to the function recited in the claim." *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1476 (Fed. Cir. 1998).

The Federal Circuit has held that a claim must be "definite" enough to be understood by one skilled in the art:

> We have stated the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2.

Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (citing *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Id. See also Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, No. C

03-1431 SBA, 2006 U.S. Dist. LEXIS 36788, at *51 (N.D. Cal. May 24, 2006). As the party asserting invalidity, Xoft bears the burden of proving indefiniteness. Moreover, because patents enjoy a statutory presumption of validity, Xoft's burden is heightened – it must prove its case with clear and convincing evidence. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986). A claim is not indefinite merely because it poses a difficult issue of claim construction (which is not even the case here, where construction is straightforward); if the claim can be construed at all, then it is not invalid for indefiniteness. *See, e.g., Bancorp Servs., LLC v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1371 (Fed. Cir. 2004). Thus, the biased, conclusory statements of Xoft's expert alone cannot establish indefiniteness by clear and convincing evidence. *See Intel Corp. v. VIA Techs.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003) (expert's conclusory statements are insufficient to provide clear and convincing evidence of indefiniteness).

CONSTRUCTION OF CLAIM TERMS[2]

I. TERMS IN THE '813 PATENT

The claims of the '813 patent relate to an instrument comprising a concentric arrangement of an inner spatial volume and an outer spatial volume defined by an inflatable chamber, disposed near the distal end of a catheter body. One of the volumes contains a source of radiation, while the other volume may contain a radiation absorptive material. In one preferred embodiment, shown in Figure 1 of the patent, the inner volume is defined by an enclosed chamber surrounding the catheter body and containing a radioactive source. The outer chamber, concentric with the inner volume, is then inflated with air or other radiation absorbing material so that its wall contacts the wall of the surgical cavity substantially at all points. The distance between the radiation source and the wall of the outer chamber can be made constant. This embodiment permits the controlled delivery of radiation to a layer of tissue surrounding the surgical cavity.[3] By manipulating the volume and type of material in the outer

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[2] Cytyc addresses herein only those terms about which the parties disagree and which Cytyc believes to be material to resolution of this suit. As to terms not addressed, Cytyc's position is as set forth in the parties' Joint Claim Construction Statement, which Cytyc incorporates by reference herein.

[3] The tissue to be treated and the resected cavity can be thought of as an orange peel with the fruit (*i.e.*, the tumor) removed. A radiation source is placed within the space previously occupied by the fruit. The thickness of the "orange

(Continued...)

chamber, the ratio of the absorbed dose at the surface of the wall of tissue to the dose at the tissue depth where the minimum dose is prescribed to be received can be controlled so as to maximize the effectiveness of the treatment and minimize adverse side effects, namely, unwanted necrosis of healthy tissue.

The '813 patent teaches that other embodiments can be used to deliver therapeutic radiation to the layer of tissue surrounding the surgical cavity. (Col 2:64 – 4:20; FIGS. 3-5.) These other embodiments include the use of a radioactive liquid within an inner inflatable chamber, a plurality of radioactive solid particles, a slurry of a fluid containing particles of a radioactive isotope or a solid radioactive source. Alternatively, these same radiation sources can be placed in the volume of space between the inner chamber and the outer inflatable chamber. Any of these embodiments might be used as a means of delivering radiation to tissue within the wall of a surgical cavity.

A. "Inner Spatial Volume" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
A region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber.	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device.

Xoft's attempt to limit the "inner spatial volume" to a "balloon" or a "spherical solid radionuclide" should be rejected. As an initial matter, a "balloon" is not even one of the embodiments of the "inner spatial volume" described in the specification. Rather, the specification describes, as an exemplary embodiment, that "the inner spatial volume 30 . . . *may* be defined by a generally spherical polymeric film wall 32." (Col. 2:35-36 (emphasis added).) In any event, it is improper to limit the claim language to the embodiments in the specification, as Xoft proposes. *Phillips*, 415 F.3d at 1323 ("For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

(...Continued)

peel" corresponds to the thickness of the tissue to be treated – in most procedures the "orange peel" of tissue to be treated is about 2 centimeters thick. (*See, e.g.*, '813 patent at FIG. 4.)

More fundamentally, Xoft confuses the tangible structure that defines the inner spatial volume with the volume itself. The specification provides that the inner spatial volume 30 "may be *defined by* a generally spherical polymeric film." The film defines the boundary of the volume but the volume is the region of space within that boundary. (Exhibit C to the Declaration of Henry C. Su (American Heritage College Dictionary ("AHC")) at 1513.) Thus, according to the specification, the inner spatial volume is simply a region of space surrounded by an outer spatial volume. (*See* col. 1:52-55 ("a first spatial volume at the distal end of a catheter and a second spatial volume defined by a surrounding of the first spatial volume by a polymeric film wall . . . .").)

Cytyc's proposed construction fully captures the plain meaning of "inner spatial volume," which the Federal Circuit notes is of "primary importance" in claim construction. *Phillips*, 415 F.3d at 1312. A "spatial volume" is a commonly understood English term, meaning simply "a region of space." (AHC at 1513.) The word "inner" means that that region of space is located within something else, and the specification provides that that "something else" is another (outer) "spatial volume." (Col. 1:52-55.) "Inner spatial volume" should therefore be construed to mean "a region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber."

B. "Outer, Closed, Inflatable Chamber" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Inflatable balloon, i.e., deflated balloon.

Cytyc believes that no construction of this term is required or appropriate. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence. There is no evidence of any intent by the inventors to impart a novel or special meaning to the term and Xoft has pointed to none. As discussed above with respect to an "inner spatial volume," Xoft's construction improperly attempts to limit the claim term to just a balloon. But nothing in the specification limits the outer, closed inflatable chamber to a "balloon." Xoft's proposed construction is not supported by the specification and is contrary to law. Cytyc proposes the term be given its plain meaning: an "outer, closed, inflatable chamber." Examples of such a chamber include an inflatable balloon or an expandable cage, and as Dr. Verhey points out, an "inflatable chamber of any type"

could satisfy this limitation. This, Xoft's proposed construction should be rejected and the plain meaning of the term adopted.

C. "Predetermined Constant Spacing" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite. "Predetermined" spacing is some undefined constant spacing predetermined in some undefined manner with regard to deflated outer chamber.

Cytyc addresses the construction of this term in connection with its construction of the term "a predetermined constant spacing between said inner spatial volume and the radiation transparent wall" below. Cytyc believes that a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate. *See Phillips*, 415 F.2d at 1314 ("Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms. . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive.") (citing *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms")).

Xoft proposes no construction of this term, arguing that it is indefinite. Contrary to Xoft's assertion, the term "predetermined constant spacing" is not indefinite and has an ordinary and customary meaning to one skilled in the art. Dr. Verhey easily understood the phrase "predetermined constant spacing" – indeed, any speaker of English can understand it – to mean that the spacing between the inner spatial volume and the wall of the outer inflatable chamber is made to be substantially constant. This spacing is "predetermined" in the sense that it is chosen in advance by one skilled in the art. (Exhibit C at 1077.) Although Xoft incorrectly suggests that the patent must describe that amount of spacing, a patent does not need to describe what one skilled in the art already knows. *See S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001) ("The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. . . . To hold

otherwise would require every patent document to include a technical treatise for the unskilled reader.") (citation omitted). One skilled in the art knows how to determine an appropriate "predetermined constant spacing." Xoft cannot possibly show that the term is indefinite by clear and convincing evidence.

D. "Predetermined Constant Spacing Between Said Inner Spatial Volume And The Radiation Transparent Wall" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The spacing between the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, can be made constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical.	Indefinite. *See* "predetermined constant spacing," *supra*, § I.C.

Xoft proposes no construction of this term, arguing only that it is indefinite. The conclusory statement of Dr. Lovoi, who works for Xoft and thus cannot provide a neutral opinion, does not come close to providing the clear and convincing evidence needed for Xoft to show indefiniteness. To the contrary, the term is readily understood by those skilled in the art. As Dr. Verhey explains, the term means that the spacing between the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, can be made constant. If the outer chamber is spherical, then the distance is constant in all directions. If the outer chamber is cylindrical, then the distance is constant around a radial plane that is perpendicular to the axis of the catheter. (Verhey Rep. at 7:2-5.) This plain meaning construction should be adopted. *Phillips*, 415 F.3d at 1312 (plain meaning is of "primary importance").

E. "Rendering Uniform" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Making the same, i.e., causing to have the same value or characteristic at all points.

Cytyc addresses the construction of this term in connection with its construction of the term "means . . . for rendering uniform the radial absorbed dose profile of the emissions" below. Cytyc

believes that a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate. *See Phillips*, 415 F.3d at 1314.

F. "Means . . . For Rendering Uniform The Radial Absorbed Dose Profile Of The Emissions " (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Disputed Function: Modifying the ratio of the absorbed dose at a depth of interest in the target tissue to the absorbed dose at the surface of the tissue.	*Disputed Function*: Making the dose along a radius extending from the radionuclide outwardly from the outer chamber wall the same at every point on the radius.
Disputed Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfite.	*Disputed Structure*: No such means disclosed in the '813 patent, means for making more uniform disclosed as substance within outer chamber.

Because this is a "means-plus-function" limitation subject to 35 U.S.C. § 112, ¶ 6, the Court must construe the limitation's function as well as the structure disclosed in the specification that corresponds to that function. *BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, L.L.C.*, 303 F.3d 1332, 1343 (Fed. Cir. 2002) (Construction of a means-plus-function limitation "requires the court to first identify the function of the means-plus-function limitation and next identify the corresponding structure in the written description necessary to perform that function."). The function required by this limitation is "rendering uniform the radial absorbed dose profile of the emissions." As Dr. Verhey explains, the radial absorbed dose profile is defined as the absorbed dose in tissue, varying as a function of distance from the center of the cavity along a particular direction of interest. (Verhey Rep. at 6:21-23.) In the '813 patent, the direction of interest would be from the wall of the surgical cavity to a depth in the target tissue at which a prescribed therapeutic dose is defined. (*Id.*) These profiles are shown as lines 40 and 42 in the '813 patent at Figure 4, reproduced on the next page and annotated for discussion purposes:

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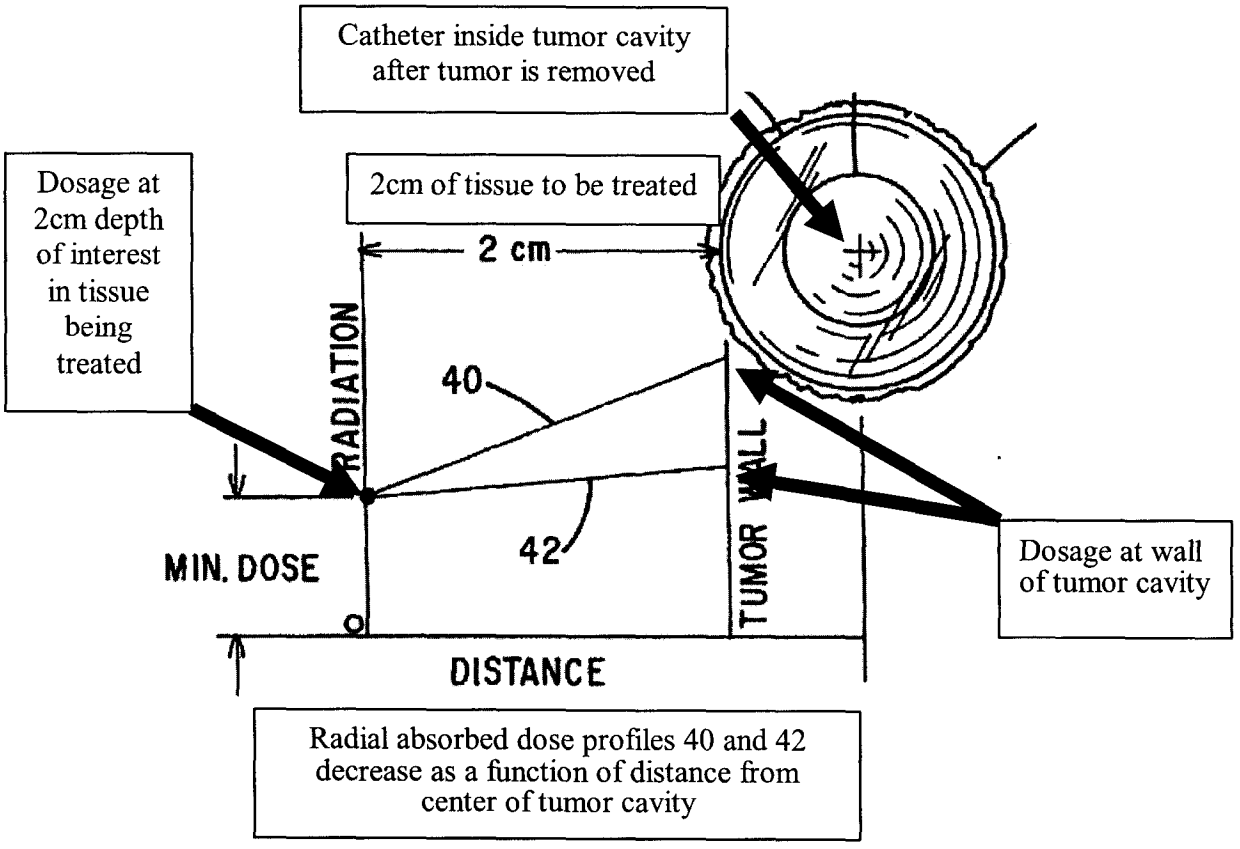

The patentees have defined in the specification what they mean by "rendering uniform the radial absorbed dose profile of the emissions." *Phillips*, 415 F.3d at 1316 (claims must be read in light of the specification). In Figure 4, line 40 is a plot of the absorbed dose as a function of radial distance that would be obtained if there were no structure defining an inner volume, *i.e.*, if the entire spherical volume of the tumor were completely filled with radioactive fluid. (Col. 3:20-24.) Plot 42, by contrast, shows the absorbed dose as a function of radial distance when the radioactive fluid is contained within an inner volume (defined by a polymeric film wall) and is surrounded by a radiation absorbing material contained in the outer volume. (Col. 3:24-28.) According to the specification, "[c]omparing plots 40 and 42, by providing the concentric arrangement depicted, the absorbed dose profile in the space between the 2cm site and the wall of the outer balloon is maintained *much more uniform*, thus preventing over-treatment of body tissue at or close to the outer wall 36 of the instrument." (Col. 3:28-33 (emphasis added).) As Dr. Verhey explains, plot 42 in Figure 4 shows a smaller ratio of the absorbed dose at the wall of the tumor cavity to the dose at the 2cm depth of interest than plot 40. Thus, as the specification defines the term, "rendering uniform the radial

absorbed dose profile of the emissions" means modifying the ratio of the absorbed dose at a depth of interest in the target tissue to the dose at the surface of the tissue, as exemplified by the difference between the slopes of plots 40 and 42.

Xoft's construction of this function is unreasonable because it excludes the preferred embodiments shown in the specification. "A claim construction that excludes a preferred embodiment . . . is 'rarely, if ever, correct.'" *Pfizer, Inc. v. Teva Pharms.USA, Inc.*, 429 F.3d 1364, 1374 (Fed. Cir. 2005) (quoting *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005)); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (same). In the diagram in Figure 4, the radial absorbed dose profile plot 42 does not show the same dose at every point along the radius, as Xoft would require. Rather, the ratio of the dose at the cavity wall to the dose at the depth of interest is less than that for the configuration in plot 40, consistent with Cytyc's construction.

The corresponding structure disclosed in the specification for performing this function is a radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfite. *Kahn*, 135 F.3d at 1476 (holding that structure described in the specification is corresponding structure if the specification "clearly links or associates that structure to the function recited in the claim."). Xoft appears to agree, suggesting that the "substance within the outer chamber" corresponds to the function for making the radial absorbed dose profile more uniform.

G. "The Radioactive Material" (Claim 8)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The material of claim 1 containing a radionuclide.	Indefinite because no antecedent.

Again, Xoft offers no construction of this term, arguing only that it is indefinite. Xoft's argument fails. Claim 8 depends from claim 1, and it is obvious that the "the radioactive material" in claim 8 clearly refers back to "a material containing a radionuclide" described in claim 1, given that the "radionuclide" is the only radioactive material mentioned in claim 1. Anyone skilled in the art

would know that the "radioactive material" in claim 8 refers to the "material containing a radionuclide" in claim 1. Claim 8 is therefore not indefinite.

H. "A Plurality Of Radioactive Solid Particles Placed At Pre-determined Locations Within The Inner Spatial Volume To Provide A Desired Composite Radiation Profile" (Claim 12)

Cytyc's Proposed Construction	Xoft's Proposed Construction
A plurality of radioactive solid particles placed at pre-determined locations within the inner spatial volume to provide a desired dose profile that is the sum of the radiation profiles of the plurality of particles.	Static array of solid radioactive particles each placed in a single location and mounted on distal ends of separate wires. "Desired composite radiation profile" is indefinite.

Xoft's proposed construction of this term improperly imports limitations from the specification that are merely examples of the preferred embodiment. The ordinary meaning of this claim term, which Cytyc proposes as the proper construction here, follows the language of the claim: "A plurality of radioactive solid particles placed at pre-determined locations within the inner spatial volume to provide a desired dose profile that is the sum of the radiation profiles of the plurality of particles." (*See* AHC at 286 (defining composite as "made up of distinct components; compound").)

II. TERMS IN THE '204 PATENT

The '204 patent, which is a continuation-in-part of the '813 patent, describes an apparatus for brachytherapy and a method of using it for interstitial delivery of radiation to diseased cells within the interstices of the tissue surrounding the cavity created by the surgical removal of proliferative tissue. The apparatus includes a catheter body member having a proximal end and a distal end, an inner spatial volume proximate to the distal end of the catheter body member, an outer spatial volume defined by an expandable surface element proximate to the distal end of the body member, and surrounding and concentric with the inner spatial volume. In a preferred embodiment, a radiation source is disposed within the inner spatial volume.

The '204 patent describes a number of embodiments that can be used in the apparatus for delivering a therapeutic dose of radiation, including, without limitation, radioactive microspheres (FIG. 4), concentric non-spherical chambers (FIG. 5), a single solid radiation emitting material surrounded by an expandable cage defining the shape of the tumor cavity (FIG. 6), a radioactive fluid filling the

outer chamber (FIG. 7a), a radioactive fluid filling the inner chamber and the outer chamber filled with air or other radiation absorbing substance (FIG. 7b), and a single solid source surrounded by an outer chamber filled with a radiation absorbing substance (FIG. 7c). Figure 7d shows examples of radiation profiles which might be obtained by the embodiments shown in Fig. 7a-7c where the depth of interest is shown as 2cm from the surface of the outer volume. As can be seen, different embodiments can be used to vary the ratio of the dose at the prescribed depth to the dose at the wall of the cavity.

A. "Interstitial" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Site in natural or surgically created cavity in body.

Cytyc addresses the construction of this term in connection with its construction of the term "interstitial brachytherapy" below. Cytyc believes that a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate. *See Phillips*, 415 F.3d at 1314.

B. "Brachytherapy" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Radiation therapy delivered by a spatially confined radiation source at or near the site of the diseased tissue.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor or other proliferative tissue disease site.

The parties mostly agree on the definition of "brachytherapy" with two exceptions. *First*, Xoft attempts to limit brachytherapy to the use of a "radionuclide" for irradiating tissue. But radiation can be provided from sources that are not radionuclides (but that can be equivalent to radionuclides), *e.g.* an X-ray tube. (*See* Exhibit F to the Declaration of Henry C. Su (The Physics of Radiation Therapy) at 418 ("Brachytherapy is a method of treatment in which sealed radioactive sources are used to deliver radiation at a short distance by interstitial, intracavitary, or surface application.").) There is no reason to limit brachytherapy to use of a radionuclide and Xoft's construction should be rejected. *Second*, Xoft improperly attempts to limit brachytherapy to treatment of tumors or other proliferative tissue

diseases. But there is no basis for such a limitation, as radiation can be applied to any diseased tissue as a doctor believes appropriate.

C. "Interstitial Brachytherapy" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Brachytherapy applied directly to the interspaces of a body tissue, where the interspaces are not naturally occurring.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor site in a natural or surgically resected cavity in a body.

Xoft has, for almost all the other disputed terms in the '204 patent, improperly added limitations that are not supported by the terms' plain meaning or the patent specification or prosecution history. With respect to "interstitial brachytherapy," which the inventors specifically defined in the prosecution history as excluding certain types of therapies, Xoft now improperly redefines the term in a manner inconsistent with the inventors' clear statements. Xoft may not blithely ignore the intrinsic evidence.

Specifically, Xoft's attempt to include "natural" body cavities in its definition of "interstitial brachytherapy" is directly contrary to the patent's prosecution history. During prosecution of the '204 patent, in traversing a rejection from the examiner, the inventors distinguished between brachytherapy applied to a natural body cavity and interstitial brachytherapy:

> Turning to the cited prior art, the Ishiwara device comprises a thermotherapeutic apparatus having a catheter body member, an inner lumen surrounded by an outer lumen, and a radiation source contained within the inner lumen. As disclosed in col. 4, lines 19-23, Ishiwara's apparatus is inserted into a body cavity. . . . Hence the apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but rather intercavital radiation treatment.

(Exhibit E to the Declaration of Henry C. Su (12/20/00 Amendment and Response ("Amendment")) at 11 (emphasis in original; internal citations omitted).)

Similarly, with respect to another reference, the inventors distinguished intraluminal therapy from interstitial therapy:

> Weinberger discloses in Figure 17 an intercavital radiotherapy device for insertion within a patient's lumen. . . . Like Ishiwara, Weinberger's apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but instead *intraluminal* radiation treatment. Whereas Applicant's device treats disease that is

> embedded in tissue (e.g., breast cancer), Ishiwara and Weinberger treat disease in a luminal cavity. For this reason, in Ishiwara and Weinberger, the catheters and expandable balloons are very different than those of Applicant's invention.

(Amendment at 12 (emphasis in original; internal citations omitted).) In light of these clear statements, Cytyc is surprised that Xoft would even attempt to propose a construction of "interstitial brachytherapy" that included natural body cavities or lumens.

In summary, the inventors have specifically excluded "intercavital" or "intraluminal" radiation therapy – *i.e.,* insertion of a brachytherapy apparatus within a natural body cavity or lumen – from the definition of "interstitial brachytherapy." Cytyc's proposed construction comports with the plain meaning of the claim term, based on the inventors' disclaimer in the prosecution history.

D. "Inner Spatial Volume" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
.A region of space surrounded by an outer spatial volume that is defined by an expandable surface element.	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device.

Xoft's attempt to limit the "inner spatial volume" to a "balloon" or a "spherical solid radionuclide" should be rejected. A "balloon" is not even one of the embodiments of the "inner spatial volume" described in the specification. Rather, as in the '813 patent, the specification of the '204 patent describes, as an exemplary embodiment, that "the inner spatial volume 30 . . . ***may*** be defined by a generally spherical polymeric film wall 32." (Col. 3:58-59.) In any event, it is improper to limit the claim language to the embodiments in the specification, as Xoft proposes. *Phillips*, 415 F.3d at 1323 (one must "avoid the danger of reading limitations from the specification into the claim.").

More fundamentally, Xoft continues to confuse the structure that defines an inner spatial volume with the volume itself. The specification provides that the inner spatial volume 30 "may be *defined by* a generally spherical polymeric film." The film defines the boundary of the volume but the volume is the region of space within that boundary. Thus, according to the specification, the inner spatial volume is simply a region of space surrounded by an outer spatial volume. (*See* col. 2:39-45 ("The apparatus includes . . . an inner spatial volume disposed proximate to the distal end of the catheter body member, [and] an outer spatial volume defined by an expandable surface element

disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume . . . .").)

Cytyc's proposed construction fully captures the plain meaning of "inner spatial volume," which the Federal Circuit notes is of "primary importance" in claim construction. *Phillips,* 415 F.3d 1312. A "spatial volume" is a commonly understood English term, meaning "a region of space." (AHC at 1513 (defining "volume" as "the amount of space occupied by a three-dimensional object or region of space, expressed in cubic units").) The word "inner" means that that region of space is located within something else, and the specification provides that that "something else" is another (outer) "spatial volume." (Col. 1:52-55.) Thus, "inner spatial volume" should be construed to mean "a region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber."

E. "Outer Spatial Volume" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate. Alternatively: a region of space defined by an expandable surface element and surrounding an inner spatial volume.	Balloon or cage.

Cytyc believes that no construction of this term is required or appropriate. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. Thus, "outer spatial volume" should be construed to mean "outer spatial volume."

Xoft's proposed construction of the term, like its proposed construction of "inner spatial volume," confuses the outer spatial volume with the "expandable surface element" that defines its boundary. The "outer spatial volume" is a region of space that is *defined* by an "expandable surface element" but it is not the "expandable surface element" itself. (*See* col. 3:61-65.) If the Court is inclined to construe "outer spatial volume," then the term should be construed as "a region of space defined by an expandable surface element and surrounding an inner spatial volume." This is consistent with the ordinary meaning of the claim term in view of the specification.

F. "Expandable Surface Element" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate. Alternatively: a device that can be expanded or inflated, such as an expandable cage or an inflatable balloon.	Deflated balloon or collapsed cage.

Cytyc believes that no construction of this term is required or appropriate. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. "Expandable surface element" should be construed to mean "expandable surface element."

Xoft's attempt to limit the term to a "deflated balloon or a collapsed cage" is improper, and there is no support for doing so in any of the intrinsic evidence. Something that is "expandable" is capable of expansion (or inflation) and can be in any state of expansion (or inflation) from no expansion to full expansion. Indeed, as Dr. Verhey explains, a person having ordinary skill in the art would expect to have to expand the expandable surface element in order to practice the invention of the '204 patent. (Verhey Rep. at 9:17-20, 10:16-18.) A construction that limits this element to a "deflated" or "collapsed" state is unreasonable and erroneous.

G. "Radiation Source" (All Asserted Claims)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Radionuclide

Cytyc believes that no construction of this term is required or appropriate. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. A "radiation source" is simply that—a radiation source. Xoft's attempt to limit a "radiation source" to just radionuclides, a specific kind of source, is unsupportable.

H. "Minimum Prescribed Dose" (Claims 2, 18, 24, 32, & 36)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Minimum prescribed dose received within a target tissue for delivering therapeutic effects.	Minimum dose needed to treat cancer cells.

Xoft's attempt to limit this term to the provision of a dose to treat cancer cells is improper and unsupported. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. The meaning can be readily discerned from the context of the surrounding claim language – "a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue." (*See, e.g.*, col. 8:31-33.) *See also Phillips,* 415 F.3d at 1314 ("Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms. . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive.")

I. "Delivering A Prescribed Absorbed Dose" (Claim 34)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite – the patent contains no information on how to obtain a prescribed dose, much less a prescribed dose using an expandable surface element.

Cytyc believes that no construction of this term is required or appropriate. The term has its ordinary and customary meaning to one skilled in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. Contrary to Xoft's assertion, the phrase is not indefinite because a "prescribed absorbed dose" refers to the fact that the amount of the dose to be delivered to a target tissue is within the discretion (i.e., prescription) of a person with ordinary skill in the art to determine. For example, a radiation oncologist determines, using treatment planning software or some other reference or tool, the proper dosage for each patient, depending on a number of physiological factors. The patient-specific

amount of radiation is a "prescribed dose." As to how the dose is delivered, Dr. Verhey explains that "once the inflatable expandable surface element is in contact with the surface of the surgical cavity, the dose at the prescription depth can be delivered once the radiation source is introduced into the catheter." (Verhey Rep. at 9:26-28 (citing col. 5:66 – 6:28).) Delivering a prescribed absorbed dose is not indefinite and the term means exactly what it says—delivering a prescribed absorbed dose.

J. "The Inner And Outer Spatial Volumes Are Configured To Provide A Minimum Prescribed Absorbed Dose" (Claim 2 & 36) And "Configuring The Inner And Outer Spatial Volumes To Provide A Minimum Prescribed Absorbed Dose" (Claims 24 & 32)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue; and Configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue.	Indefinite – configured volumes are expanded volumes, but no cause and effect relationship between configuring of inner and outer volumes and providing dose of any prescribed amount.

Contrary to Xoft's contention, this term is not indefinite. The '204 patent discloses in detail the various ways in which a person of ordinary skill in the art can achieve a configuration of the inner and outer spatial volumes that will deliver a minimum prescribed dose to a target tissue of interest. (*See, e.g.,* col. 5:22-41; col. 6:16 – col. 7:28.) As Dr. Verhey explains:

> [W]here the radioactive material is disposed in the inner spatial volume, the rate at which the dose falls off between the surface of the surgical cavity and the depth at which the minimum dose is to be prescribed, can be controlled by modifying the quantity and type of radiation absorbing material contained within the outer spatial volume. The safe delivery of the minimum prescribed dose at the depth of interest requires that the tissue intervening between the surface of the cavity and the depth of interest receive a dose which is equal to or grater than the prescribed dose but less than that which would necrose (i.e., lethally damage) healthy tissue."

(Verhey Rep. at 8:25 – 9:3.) Because one skilled in the art knows how to configure the spatial volumes to provide the minimum prescribed absorbed dose, the term is not indefinite.

K. "A Minimum Distance Outward From The Outer Spatial Volume Expandable Surface" (Claims 2, 24, 32, & 36)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite because it is some unknown distance from deflated balloon or collapsed cage. Patent contains no information regarding determination of minimum distance.

Cytyc believes that no construction of this term is required or appropriate and that the term is definite. The term has its ordinary and customary meaning and is understood by one of ordinary skill in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term.

The meaning of "a minimum distance outward from the outer spatial volume expandable surface" is not indefinite and can be readily discerned from the context of the surrounding claim language – "the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface." The disputed phrase refers to the minimum distance outward from the expandable surface element that defines the outer spatial volume. This minimum distance defines the thickness of a layer of target tissue which, in the determination of a person of ordinary skill in the art, includes the region in which diseased cells might reside. (Verhey Rep. at 9:6-9.)

L. "Controlled Dose" (Claim 2, 24, 32, & 36)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite because configuration, i.e., expansion, of inner and outer volumes does not control dose.

Cytyc addresses the construction of this term in connection with its construction of the phrase "providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface" below. Cytyc believes that a separate

construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate.

M. "To Reduce Or Prevent Necrosis In Healthy Tissue Proximate To The Expandable Surface" (Claims 2, 24, 32, & 36)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite – patent does not describe providing a dose through expandable surface – improper functional limitation in apparatus claim.

Cytyc addresses the construction of this term in connection with its construction of the phrase "providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface" below. Cytyc believes that a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate.

N. "Providing A Controlled Dose At The Outer Spatial Volume Expandable Surface To Reduce Or Prevent Necrosis In Healthy Tissue" (Claims 2, 24, 32 & 36)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface	Indefinite because radiation dose is not provided when outer volume surface is "expandable", i.e., is a deflated balloon or a collapsed cage. Also indefinite because patent contains no information on how to provide dose that will reduce or prevent necrosis in healthy tissue. In context, the word "necrosis" and the term "necrosis in healthy tissue" are indefinite.

Xoft does not offer a construction of this disputed term; it only argues that the term is indefinite. But the term is well understood by those of skill in the art. Dr. Verhey explains that by adjusting the distance between the radiation source and the surface of the outer spatial volume, or by adjusting the type of radiation absorbing material in the outer spatial volume, the ratio of the dose at the surface of the outer spatial volume to the prescribed dose at the depth of prescription can be

controlled. (Verhey Rep. at 9:12-15.) The dose must not be so high that it causes necrosis to occur in healthy tissue that is in contact with the expandable surface; persons of skill in the art will know how high such a dose may be before a significant percentage of healthy cells necrose. (*Id.*)

O. "Adapting The Expandable Surface To Contact Tissue Surrounding The Resection Cavity To Conform The Tissue" (Claim 34)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite because expandable surface, i.e., deflated balloon or collapsed cage, neither contacts nor conforms the tissue surrounding the resection cavity. The patent contains no information on how this could be done.

Cytyc believes that no construction of this term is required or appropriate and that the term is definite. The term has its ordinary and customary meaning and is understood by one of ordinary skill in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term. The term "adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue to the desired shape of the expandable surface element" means adapting the expandable surface so that it comes into contact with the tissue forming the wall of the resection cavity and conforms that tissue to its shape. This comports with the ordinary meaning of the claim term.

Xoft's indefiniteness assertion is premised on its flawed construction of "expandable surface," which requires that the surface be in a deflated or collapsed state. The fact that claim 34, however, requires the expandable surface to contact the tissue surrounding the resection cavity establishes that Xoft's construction of "expandable surface" is erroneous. Under a proper construction, the expandable surface can be inflated or expanded to some degree so that it contacts the tissue and conforms the tissue to its shape. Dr. Verhey explains: "the volume of the expandable surface can be adjusted by inflation until the surface of the expandable volume is in contact with the surface of the resection cavity at all points. In this state, the shape of the resection cavity conforms to the shape of the expandable surface." (Verhey Rep. at 9:18-20 (citing col. 5:47-61).)

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P. "Desired Shape Of The Expandable Surface Element" (Claims 4, 26, & 34)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The desired shape of the expandable surface element.	Indefinite. Patent contains no information regarding the desired shape of an expandable surface element, i.e., a deflated balloon or collapsed cage.

Cytyc believes that no construction of this term is required or appropriate and that the term is definite. The term has its ordinary and customary meaning and is understood by one of ordinary skill in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term.

This term is not indefinite, as Xoft wrongly contends. The desired shape of the balloon is within the discretion of those skilled in the art. According to Dr. Verhey, "the desired shape of the expandable surface element is that shape which provides the predetermined constant spacing between the inner spatial volume and the conformed surface of the resection cavity." (Verhey Rep. at 9:22-24 (citing col. 5:47-61).) Examples of desired shapes described in the specification include a spherical balloon (FIG. 1) and a cylindrical balloon (FIG. 5), but the invention is not limited to any particular shape. (Col. 5:13-16.)

Q. "Predetermined Spacing" (Claims 3 & 25)

Cytyc's Proposed Construction	Xoft's Proposed Construction
No construction required or appropriate.	Indefinite because no information in patent re how to determine "predetermined spacing." Also indefinite because spacing is between inner spatial volume and expandable surface element, i.e., deflated balloon or collapsed cage.

Cytyc addresses the construction of this term in connection with its construction of the phrase "a predetermined spacing is provided between said inner spatial volume and the expandable surface element" below. Cytyc believes that a separate construction of this term divorced from the context of the surrounding claim language is neither required nor appropriate.

R. "A Predetermined Spacing Is Provided Between Said Inner Spatial Volume And The Expandable Surface Element"/ "A Predetermined Spacing Between Said Inner Spatial Volume And The Expandable Surface Element" (Claims 3 & 25)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The distance between the inner spatial volume and the expandable surface element is determined in advance.	A predetermined spacing between inner spatial volume and deflated balloon or collapsed cage is indefinite.

Cytyc believes that no construction of this term is required or appropriate and that the term is definite. The term has its ordinary and customary meaning and is understood by one of ordinary skill in the art without reference to intrinsic or extrinsic evidence, and there is no evidence of any intent by the inventors to impart a novel or special meaning to the term.

Contrary to Xoft's assertion, the term is not indefinite and has an ordinary and customary meaning to one skilled in the art. Dr. Verhey readily understood the term to mean that the spacing between the inner and outer volumes can be set to a predetermined value by modifying the level of inflation or expansion of one or both volumes. Although Xoft incorrectly suggests that the patent must describe that amount of spacing, a patent does not need to describe what one skilled in the art already knows and can practice. *See S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001). One skilled in the art knows how to determine an appropriate "predetermined spacing."

Moreover, to the extent Xoft contends that there can be no spacing between the inner volume and a deflated balloon or collapsed cage, that argument also fails. Such an argument is premised on the erroneous proposal that "expandable surface" be limited to a deflated or collapsed surface. Because that construction is inconsistent with the patent and must be rejected for the reasons set forth above (*see supra* at II.F), Xoft's indefiniteness argument must also fail.

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S. "Intraoperatively" (Claims 19 & 34)

Cytyc's Proposed Construction	Xoft's Proposed Construction
Intraoperatively Alternatively: during the surgical operation to remove proliferative tissue	After surgical removal of tumor but prior to closing the surgical site.

The parties appear to agree for the most part as to the meaning of "intraoperatively," and Cytyc could agree to Xoft's proposed construction if only the construction does not include "closing the surgical site," which is superfluous. "Intraoperatively" simply means during the surgical operation to remove the proliferative tissue. Whether the site is subsequently closed (*e.g.*, with sutures) is irrelevant.

T. "Solid Radiation Source" (Claim 16)

Cytyc's Proposed Construction	Xoft's Proposed Construction
A radiation source that has a fixed shape and volume, and is not deformable.	Solid radionuclide

Xoft again improperly attempts to limit a radiation source to a radionuclide. There are other sources of radiation besides radionuclides, and there is no basis in the intrinsic evidence for limiting the plain meaning of "radiation source" to a radionuclide. Moreover, Xoft neglects to define "solid," which refers to the fact that the radiation source that has a fixed shape and volume and is not deformable. (*See* AHC at 1295 ("of definite shape and volume; not liquid or gaseous"); Verhey Rep. at 11:8-9.)

U. "The Prescribed Absorbed Dose Is Delivered To The Target Tissue In Substantially Three Dimensions" (Claim 18)

Cytyc's Proposed Construction	Xoft's Proposed Construction
The prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose.	Prescribed absorbed dose is indefinite and substantially three dimensional is indefinite.

Contrary to Xoft's assertion, there is nothing indefinite about this limitation because one of ordinary skill in the art would understand what a prescribed absorbed dose is and how that dose can be delivered substantially in three dimensions. Dr. Verhey explains that this limitation relates to the fact that, once the outer chamber is expanded, the tissue in contact with the chamber conforms to the shape of the chamber, thereby assuring that all points within the tissue that are at a fixed distance from the wall of the surgical cavity will receive the identical dose. (Verhey Rep. at 11:12-15.) In this manner, the prescribed dose is delivered to the target tissue at the depth of interest substantially in all three dimensions, as opposed to being delivered in only two dimensions (to all points on a plane) or one dimension (to all points along a line). The limitation is clear, not indefinite, and should be given its ordinary meaning.

CONCLUSION

For the reasons stated above, this Court should adopt Cytyc's proposed constructions of the disputed terms of the '813 and '204 patents, and reject Xoft's proposed constructions and indefiniteness arguments.

Respectfully submitted,

DATED: November 9, 2006

HOWREY LLP

By: /s/ Henry C. Su
Henry C. Su

Attorneys for Defendants CYTYC CORPORATION and CYTYC SURGICAL PRODUCTS II, INC.

CERTIFICATE OF SERVICE

As required by Civil Local Rule 5-6(a)(2), the undersigned hereby certifies that on November 9, 2006, a true and correct copy of:

DEFENDANT AND COUNTERCLAIMANT CYTYC CORPORATION'S OPENING CLAIM CONSTRUCTION BRIEF (PAT. L.R. 4-5(a))

was served on the following counsel of record for Xoft, Inc. electronically through this Court's Electronic Case Filing System, in accordance with Civil Local Rule 5-5(b):

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Exhibit 4

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

DECLARATION OF LYNN J. VERHEY, Ph.D. IN SUPPORT OF PLAINTIFFS' PROPOSED CONSTRUCTION OF CLAIM TERMS, PHRASES AND CLAUSES

I, Lynn J. Verhey, Ph.D., declare and state as follows:

I have been retained in this case as an expert witness by Plaintiffs Hologic, Inc., Cytyc Corporation, and Hologic L.P ("Hologic"). I make this declaration based on my personal knowledge, training and experience, and if I were to be called to testify, I could and would testify competently about the subject matter set forth below.

I understand that the parties propose different constructions of various terms, phrases and clauses in the patents-in-suit. I submit this declaration to provide my opinion on the meaning of the disputed claim terms.

I. INTRODUCTION AND MY EXPERT QUALIFICATIONS

On April 3, 2008, in support of Hologic's Motion for Preliminary Injunction, I submitted a declaration describing my current employment and summarizing my background and education. Ex. A (¶¶ 3-7) (Dkt. No. 77). I have also submitted a current curriculum vitae to the Court. Ex. B. In the April 3, 2008 declaration, I explained that I previously served as an expert witness for Cytyc Corporation (Cytyc has since been acquired by Hologic) in the case of *Xoft, Inc. v. Cytyc Corporation and Proxima Therapeutics, Inc*., Case No. C05-05312 RMW (¶ 8) (the "Xoft litigation"). The Xoft litigation involved United States Patent Nos. 5,913,813 (the "'813 patent") and 6,413,204 (the "'204 patent"), both of which are at issue in this case.[1] In that declaration, I also briefly described the subject matter of the three patents-in-suit. Ex. A at ¶ 9. Rather than repeating those statements again, I incorporate the contents of my April 3, 2008 declaration by reference.

II. TOPICS THAT I HAVE BEEN ASKED TO ADDRESS

I have been asked to provide opinions regarding how a person of ordinary skill in the art would interpret the meaning of certain claim terms and phrases from the '813, '204 and '142 patents.

III. INFORMATION CONSIDERED IN FORMING MY OPINIONS

On October 12, 2006, I submitted a declaration in the prior Xoft litigation relating to claim construction issues in that case. Ex. C. A substantial part of that declaration is relevant to the present

[1] A third patent, United States Patent No. 6,482,142 (the "'142 patent"), is also at issue in this case.

case. Rather than repeating those statements again, I incorporate the contents of my October 12, 2006 declaration by reference. Ex. C. Therein, I identified the information I considered in forming my claim construction opinions. *Id.* at 2-3. I have considered the same information here, with the following additions: (1) I have reviewed and considered the text of the '142 patent and the file history associated with its issuance; (2) I have reviewed and followed the claim constructions that the Court issued in the Xoft case for the '813 and '204 patents; and (3) I have reviewed and considered the claim constructions proposed by the parties in this case. I have not reviewed any written or oral opinions from any expert whom SenoRx has retained or may retain in connection with this case. I reserve the right to modify my opinions stated in this declaration after having reviewed any such opinion offered by any such expert. I also reserve the right to modify my opinions based on any rulings that the Court might issue in the future relating to these patents.

IV. APPROACH I HAVE USED IN READING THE '813, '204, AND '142 PATENTS AND INTERPRETING THEIR CLAIMS

In my October 12, 2006 declaration (Ex. C), I explained my methodology for interpreting claim terms and phrases from the '813 and '204 patents. The statements made in that declaration with regard to my approach to claim construction apply equally to the present case.

This case involves one additional patent and different asserted claims. I understand that the claims of the '813 patent at issue in this lawsuit are claims 11 and 12, found in columns 5 and 6 of the patent. I understand that the claims of the '204 patent at issue here are claims 4 and 17, found in columns 8 and 9 of the patent. I understand that the claims of the '142 patent at issue here are claims 1, 6 and 8, found in columns 8, 9, and 10 of the patent. I understand that all three patents are related to one another by lineage, with the '813 patent being the parent. The '204 and '142 patents are continuations-in-part of the '813 patent.

V. LEVEL OF SKILL OF ONE OF ORDINARY SKILL IN THE ART

In my October 12, 2006 declaration (Ex. C), I identified the skill level of one of ordinary skill in the art for purposes of interpreting the claims of the '813 and '204 patents. *Id.* at 4. The same skill level would apply to construing the '142 patent claims.

VI. THE MEANING OF THE DISPUTED CLAIM TERMS IN THE '813, '204, AND '142 PATENTS

I have reviewed and relied upon the material identified in Section III above. Based on these materials, my knowledge and experience in the technical field to which the patented inventions relate, and my familiarity with the level of ordinary skill in the art at the times the applications for the '813, '204, and '142 patents were filed, I have formed opinions as to how one of ordinary skill in the art would have interpreted certain claim terms at the time of their invention. My opinion regarding the meaning of each of the disputed claim terms is set forth below. Where the disputed term is present in more than one of the asserted patents, my interpretation is given only once. The list of disputed terms includes those identified by either party. For a few of the terms, I provide an explanation of why I disagree with SenoRx's proposed construction.

VII. TERMS ALREADY CONSTRUED IN THE PRIOR XOFT LITIGATION

I notice that SenoRx disputes a number of claim terms that the Court already construed in the prior Xoft litigation. I will not address those terms already construed by the Court. I reserve the right to address them at a later point in time if appropriate.

The '813 Patent

"inner spatial volume" (claims 1, 2, and 12) - The Court previously construed this term to mean "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide." Col. 1:50-2:3; 2:33-63; 3:9-16, 42-48; 3:64-4:12; 4:16-30, 32-52; 6:6-7; Figs. 1, 3-5; Decl. of Katharine Altemus in Support of Plaintiffs' Opening Claim Construction Brief ("Altemus Decl.") at 3-5, 28 (Claim Construction Order from *Xoft, Inc. v. Cytyc Corp. et al.*) I address this term again only to respond to a particular problem I see with SenoRx's proposed construction.

SenoRx proposes to modify the Court's construction to limit, for embodiments where the "inner spatial volume" is defined by the outside surface of a solid radionuclide, the radionuclide to a "sphere." This is an artificially narrow construction, which does not accurately reflect standard brachytherapy treatment. One skilled in the art of brachytherapy would know that in a typical brachytherapy procedure using a solid radionuclide, the radionuclide is not necessarily spherical in

shape and does not need to be. This was also true in 1997, when the application for the '813 patent was filed. Therefore, to so limit the definition of the term "inner spatial volume" does not accurately reflect standard practice. Nor does it comport with the claim language, which does not include or imply such limiting language.

"inner, closed chamber" (claim 2) – One of ordinary skill in the art would understand this term as written – i.e., it means "inner, closed chamber." No further elaboration or explanation is needed.

It does not make sense from a technical standpoint to say that the inner spatial volume must be "completely" inside the outer chamber or "closed off within the outer chamber," as SenoRx suggests. Clearly, as seen in the text of the '813 patent, Col. 2:36-38, and as commonly understood in the field, an inner spatial volume that is an inner, closed chamber defined by a radiation transparent wall must still permit a radiation source to be placed in there. If it were completely sealed or closed off, that would not be possible.

The '204 Patent

"three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" (claim 1) – means exactly that, "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element." One of ordinary skill in the art would understand this term as written. No further elaboration or explanation is needed.

"plurality of solid radiation sources" (claim 17) – means exactly that, "plurality of solid radiation sources." One of ordinary skill in the art would understand this term as written. No further elaboration or explanation is needed.

"isodose profile having a shape substantially similar to the shape of the outer spatial volume" (claim 17) – means exactly that, "isodose profile having a shape substantially similar to the shape of the outer spatial volume." One of ordinary skill in the art would understand this term as written. No further elaboration or explanation is needed.

The '142 Patent

"three-dimensional apparatus volume configured to fill an interstitial void" (claims 1 and 8) – In my opinion, this claim phrase can only be understood in the context of the limitation in which it

appears and is a part of. This limitation is "an expandable outer surface *defining* a three-dimensional apparatus volume *configured to fill* an interstitial void created by the surgical extraction of diseased tissue *and define* an inner boundary of the target tissue being treated." As the italicized language makes clear, the "three-dimensional apparatus volume" is something that is defined by the "expandable outer surface." What this expandable outer surface defines is a three-dimensional geometric solid (e.g., a sphere) having both volume that fills an interstitial void created by the surgical extraction of diseased tissue and a surface area that defines an inner boundary of the target tissue being treated. Accordingly, in my opinion, the term "three-dimensional apparatus volume" means "a three-dimensional geometric solid composed of an expandable outer surface." By "solid," I mean a geometric shape, such as a sphere, having three dimensions and a surface area.

In my opinion, SenoRx construes this claim term divorced from its context. I agree that the patentee's use of the word "volume" here is somewhat unusual. However, it is clear from the context that the patentee uses the term "apparatus volume" to refer to a three-dimensional geometric solid or shape defined by the expandable outer surface rather than "a region of space within the expandable outer surface" – as SenoRx's suggests. Col. 2:20-53, 60-64; 3:20-36, 55-62, 66-67; 4:1-2, 27-42; 5:36-65; 6:11-29; 8:1-32, 52-59, Figs. 1, 3-4.

"<u>located so as to be spaced apart from the apparatus volume</u>" (claim 1) – Like the preceding claim phrase, this claim phrase can only be understood in the context of the limitation in which it appears and is a part of. This limitation is "a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume." As noted above, the three-dimensional apparatus volume is a geometric solid defined by the expandable outer surface that has both volume and surface area. Understood in this context, the phrase "located so as to be spaced apart from the apparatus volume" logically refers to the surface area of the apparatus volume that defines the inner boundary of the target tissue being treated. Accordingly, in my opinion, this claim phrase means "located so as to be not on or touching the apparatus volume." Col. 2:20-53; 3:20-25, 55-62, 66-67; 4:1-2, 27-30, 35-57; 5:36-65; 6:11-29; 7:1-15, 49-55; 8:1-32, 52-59; Figs. 1, 3-4.

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"asymmetrically located and arranged within the expandable surface" (claim 1) – means "located and arranged so as not to be on the longitudinal axis of the expandable surface." Col 2:20-53; 3:7-19, 55-62, 66-67; 4:1-2; 5:12-37; 6:11-29, 24-67; 7:1-15; 8:1-32, 52-59; Figs. 1, 3-4.

"predetermined asymmetric isodose curves" (claims 1, 6 and 8) – means "predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume." Col. 2:20-53; 2:60-3:1; 3:7-19; 5:12-37; 6:11-29, 24-67; 7:28-48; 7:62-8:32; 8:52-59.

"plurality of solid radiation sources" (claim 6) – means exactly that, "plurality of solid radiation sources." One of ordinary skill in the art would understand this term as written. No further elaboration or explanation is needed.

"being provided on at least two elongate members extending into the apparatus volume" (claim 6) – means exactly that, "being provided on at least two elongate members extending into the apparatus volume." One of ordinary skill in the art would understand this term as written. As explained above, the three-dimensional apparatus volume defined by the expandable outer surface is a geometric solid that has both volume and surface area. In the context of this limitation, it is clear the two elongate members are extending into the volume of this geometric solid.

I declare that the foregoing is true and correct to the best of my knowledge under penalty of perjury.

Executed on May 21, 2008 in San Francisco, California.

Lynn J. Verhey, Ph.D.